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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,816	01/12/2007	Daniela Montanari	163-709	4931

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
05/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,816	MONTANARI ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,7 and 10-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,7 and 10-23* is/are rejected.

7)☒ Claim(s) *24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 March 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election of the species Tyr-Arg in the reply filed on May 4, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The disclosure is objected to because of the following informalities: A SEQ ID NO must be inserted after each occurrence in the specification of an amino acid sequence subject to the sequence disclosure rules. See 37 CFR 1.821(d). Such a sequence is present at page 9, line 15, of the specification. In the amended paragraph beginning at page 19, line 23, of the specification, at line 3 of the amended paragraph, the "®" symbol which occurred after "Botoina" has been changed to ".rtm." without marking. The "®" symbol should be re-inserted into the paragraph. Appropriate correction is required.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6, 7, and 11-21 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the limitation "wherein said sodium and potassium are derived from a natural source" which has been inserted into claim 1. There is no literal support for the limitation in the original disclosure of the invention. Applicants point especially to pages 12-13 of the specification and to originally filed claim 10 as

support for the new claim limitation. However, these sections of the disclosure use the term "natural source" only as part of a description of anise extract. The term is not used by Applicants to disclose a subgenus of sodium and potassium compounds. (Note that Applicants' reference to sodium and potassium salts in the arguments is in error, as the claims do not make any mention of salts.)

4. Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 is unclear because it requires the presence of "at least one peptide", but also recites that the at least one peptide comprises a pentapeptide and a dipeptide, which is two peptides. The recitation of "at least one peptide" contradicts the requirement of two peptides. In view of Applicants' arguments, it is believed that the "at least one peptide" language should be omitted from the claim. There is no antecedent basis in the claims for the phrase "the mixture of sodium-potassium micro-elements" at claim 23, line 2.

5. Claim 1, 6, 7, and 10-23 are objected to because of the following informalities: At claim 1, line 5, "SEQ ID NO 1" should not be subscripted. At claim 12, line 2, "an" should be changed to "a". At claim 22, line 4, "a pentapeptide of" is non-idiomatic. At claim 22, line 5, "the" should be changed to "a" in order to avoid issues of lack of antecedent basis. Appropriate correction is required.

6. It should be noted that if the limitation "wherein said sodium and potassium are derived from a natural source" is deleted from claim 1, the result will be that claims 24 and 25 will be identical in scope with claims 13 and 14, respectively. Under such circumstances, the examiner

will have to consider the appropriateness of an objection under 37 CFR 1.75 on the basis of duplicate claims.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1, 6, 7, 15, 19, and 21 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 2004/0132667). Lintner et al teach a composition comprising potassium sorbate, sodium hydroxide, and Calmosensine®. Potassium sorbate and sodium hydroxide correspond to Applicants' micro-element. The composition is in the form of a cream. Lintner et al's compositions in general are intended to treat wrinkles in facial skin and hands and signs of skin aging, and can be in any physical form. See, e.g., the Abstract; paragraphs [0035] and [0297]; and Example 4, paragraph [0317]. Lintner '667 teaches (see paragraph [0095]) that the Calmosensine® of Lintner et al is a synonym for N-Acetyl-Tyr-Arg-hexadecyl ester, which is Applicants' elected and preferred dipeptide species. The facial wrinkles due to skin aging taught by Lintner et al correspond to Applicants' expression wrinkles. Because of the identity of components and method steps between Lintner et al and Applicants' claimed convention, inherently the N-Acetyl-Tyr-Arg-hexadecyl ester of Lintner et al will exhibit decontracting action on muscular fibers present in wrinkles, and inherently the potassium sorbate and sodium hydroxide of Lintner et al will reduce contraction of a muscular fiber present in wrinkles, to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the composition and method of Lintner et al and Applicants' claimed compositions and methods to shift the burden to Applicants to provide evidence that the

claimed compositions and methods are unobviously different than those of Lintner et al. Note that more fully disclosing a biochemical mechanism by which a prior art composition or method works, or disclosure of properties inherent in a prior art composition, does not constitute a basis for patentability. With respect to the limitation "wherein said sodium and potassium are derived from a natural source", it should be noted that this is a process limitation, and process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art. Further, note that the words "derived from" in the limitation mean that sodium and potassium are ultimately obtained from a natural source, and do not mean that the sodium and potassium are in a form found in nature. This interpretation of "derived from" is consistent with Applicants' identification of anise extract as being derived from a natural source. Anise extract is not a natural source per se, but rather is "derived from" anise after at least one processing step, i.e. aqueous extraction. In this sense, the sodium and potassium present in the sodium hydroxide and potassium sorbate of Lintner et al are ultimately "derived from" a natural source of sodium and potassium, e.g. sodium and potassium obtained by mining or from sea water.

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 0132/667). Application of Lintner et al and Lintner '667 is the same as in the above rejection of claims 1, 6, 7, 15, 19, and 21. Lintner et al do not specifically exemplify a composition comprising Calmosensine® in the form of liposomes, although in general Lintner et al teach that their compositions can be administered in the form of liposomes. See, e.g., paragraph [0059] and claim 32. It would have been obvious to one of ordinary skill in the art at

the time Applicants' invention was made to administer the Calmosensine®-containing compositions of Lintner et al in the form of liposomes, because Lintner et al teach that liposomes have general utility for administering their compositions, and because the physical form of Lintner et al's active agents would not have been expected to affect materially the biochemical effects which Lintner et al's active agents have on wrinkles.

10. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being obvious in view of Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 2004/0132667) as applied against claims 1, 6, 7, 15, 19, and 21 above, and further in view of Sojka (U.S. Patent Application Publication 2005/0002996), Patt (U.S. Patent Application Publication 2006/0052287), and Renault (U.S. Patent Application Publication 2004/0147443). Lintner et al do not teach the inclusion of sodium gluconate, potassium gluconate, and magnesium gluconate in their compositions. Sojka teach sodium gluconate to be a known skin conditioning agent. See, e.g., paragraph [0056]. Patt teach potassium gluconate to be a known skin protectant. See paragraph [0048] and page 18, lines 7-10, of its provisional application 60/602,715. Renault teaches compositions comprising magnesium gluconate for the treatment of expression wrinkles. See, e.g., paragraphs [0085] and [0104], and Examples 1-2. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include the sodium gluconate, potassium gluconate, and magnesium gluconate of Sojka, Patt, and Renault in the compositions of Lintner et al, because each of the components is known to be useful in treating skin, and because the use of combinations of known skin treating components in cosmetic compositions is routine in the cosmetic art.

11. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being obvious in view of Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 2004/0132667) as applied against claims 1, 6, 7, 15, 19, and 21 above, and further in view of Laversanne et al (U.S. Patent No. 6,277,404). Lintner et al teach that their compositions can be administered in any physical form, but do not teach a physical form which is a multilamellar liposome having a dimension ranging from 150-500 nm. Laversanne et al teach substantially spherical multilamellar vesicles, i.e. liposomes, having a dimension of 0.1 to 100 μm, i.e. 100 to 100,000 nm, and carrying a positive charge so that a cosmetically active agent will more readily adhere to the skin of a subject being treated. Active agents to be administered include peptides. See, e.g., the Abstract; column 4, lines 14-17 and 20-30; and column 7, lines 20-25. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer the composition of Lintner et al in the form of a multilamellar vesicle as taught by Laversanne et al, because Lintner et al's compositions are not required to be administered in any particular physical form, and because Laversanne et al show that multilamellar vesicles are known to be useful for applying cosmetic agents to skin and can have the benefit of allowing better adherence of the cosmetic agents to the skin.

12. Claim 20 is rejected under 35 U.S.C. 103(a) as being obvious in view of Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 2004/0132667) as applied against claims 1, 6, 7, 15, 19, and 21 above, and further in view of Donovan (U.S. Patent Application Publication 2005/0074461) or the Japanese Patent Application 2004-197234. Lintner et al teach a composition for treating wrinkles in facial skin and hands, but do not teach Applicants' claimed apparatus for

administering the composition. Donovan teaches administering compositions topically to a person's skin using syringe without needles so as to prevent the compositions from contacting the fingers of the person. See paragraph [0073]. The Japanese Patent Application '234 teaches a syringe for applying liquid cosmetics to the skin. See, e.g., the attached abstract. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the syringes of Donovan or the Japanese Patent Application '234 to apply the composition of Lintner et al, because Donovan and the Japanese Patent Application '234 teach known apparatus for applying cosmetics to skin, the same purpose taught by Lintner et al, and because the particular apparatus used to administer Lintner et al's composition would not have been expected to affect materially the cosmetic properties of the composition.

13. Applicant's arguments filed March 8, 2010 have been fully considered but they are not persuasive.

The anticipation rejection based upon Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 2004/0132667) is maintained. Assuming, arguendo, that the limitation "wherein said sodium and potassium are derived from a natural source" is supported by the original disclosure of the invention and is to be accorded more patentable weight than a typical process limitation in a product-by-process claim, Lintner et al still teach sodium and potassium which are "derived from" a natural source. See the analysis which has been added to the anticipation rejection.

With respect to the obviousness rejection based upon Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 2004/0132667) and further in view of Sojka (U.S. Patent Application Publication

2005/0002996), Patt (U.S. Patent Application Publication 2006/0052287), and Renault (U.S. Patent Application Publication 2004/0147443), Applicants correctly argue that Sojka and Patt do not disclose their sodium and potassium gluconates in combination with a peptide, and that Renault does not teach sodium and potassium from a natural source. However, as Sojka, Patt, and Renault are not applied individually against Applicants' claims, these arguments do not require withdrawal of the obviousness rejection. These arguments do not address or contradict the essence of the obviousness rejection, i.e. that it is obvious to add known cosmetic ingredients to a cosmetic composition with only the expected gain of function.

The obviousness rejection based upon Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 2004/0132667) and further in view of Donovan (U.S. Patent Application Publication 2005/0074461) or the Japanese Patent Application 2004-197234 is maintained. Paragraph [0073] of Donovan, cited in the rejection, discloses multiple application devices capable of administering a composition topically to a patient's skin while preventing contact of the composition with the patient's fingers. The devices disclosed in this paragraph were not invented by Donovan for the administration of his botulinum compositions, and the benefit of these devices is not limited to administration of the botulinum compositions of Donovan. The Japanese Patent Application '234, applied in the alternative to Donovan, also teaches application devices not limited to the administration of botulinum compositions.

Applicants' response includes Exhibits A and B, providing comparative experimental data between dipeptide + anise extract and dipeptide + sodium hydroxide + potassium sorbate (Lintner et al's composition); and between dipeptide + magnesium gluconate and dipeptide +

sodium hydroxide + potassium sorbate (Lintner et al's composition). Firstly, because the data was not submitted in appropriate affidavit or declaration form under 37 CFR 1.132, it can not be relied upon to rebut any prima facie case of obviousness established by the prior art. Secondly, with respect to the first set of comparative experimental data, because none of the rejected claims is limited to compositions comprising anise extract, the comparative experimental data is not commensurate in scope with the rejected claims and can not serve to rebut the obviousness rejections. Finally, with respect to the second set of comparative experimental data, the results appear to be consistent with and expected in view of the teachings of Renault (U.S. Patent Application Publication 2004/0147443). Renault teaches that expression wrinkles are caused by contraction or hypercontraction of facial muscles and/or contractile cells of the dermis, and that the contraction or hypercontraction is caused by Ca^{2+} (see, e.g., paragraph [0027]); and teaches that the effects of magnesium are generally antagonistic to those of calcium (see, e.g., paragraph [0084]). In view of Renault, the results shown in Exhibit 2 do not appear to be unexpected. There is an issue as to whether the experimental data in Exhibit 2 is probatively comparative, because of the significantly greater amounts of magnesium gluconate used relative to the amounts of sodium hydroxide and potassium sorbate. There is also an issue as to whether the experimental data in Exhibit 2 is commensurate in scope with those of Applicants' claims which require the presence of magnesium gluconate, i.e. claims 11 and 12. Exhibit A sets forth the results of replacing sodium hydroxide and potassium sorbate with magnesium gluconate, whereas the claims embrace use of combinations of all three compounds.

14. Claims 24 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 22 and 23 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and the claim objections set forth in this Office action.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal

communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
May 26, 2010